March 2004

THE KENTUCKY LABORATORY SENTINEL

Celebrate National Medical Laboratory Week!! April 18-24

BOTULISM

In the United States an average of 110 cases of botulism are reported each year. Of these, approximately 25% are foodborne, 72% are infant botulism, and the rest are wound botulism. Outbreaks of foodborne botulism involving two or more persons occur most years and are usually caused by eating contaminated home-canned foods. The number of cases of foodborne and infant botulism has changed little in recent years, but wound botulism has increased because of the use of black-tar heroin, especially in California.*

*Excerpted from CDC website

The Kentucky State Public Health Lab annually tests 1-2 specimens for botulism. Although the numbers are not high, this is a necessary test. If your facility has a patient that needs to be tested for botulism, please follow these simple steps:

- Patient's physician must consult the Division of Epidemiology to verify the need to perform appropriate tests.

This is the most important part of the process. Testing for Botulism is very expensive and labor intensive. The patient must first be tested to rule out other organisms.

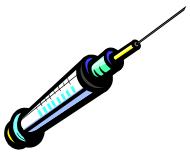
- Consult with Laboratory Services for specific information on collecting and submitting specimens.

SHARPS INJURIES

(APHL E UPDATE FEBRUARY 26, 2004)

CDC is offering a new tool to protect healthcare personnel from injuries caused by needlesticks and other sharp instruments. CDC estimates that hospital workers sustain more than 1,000 injuries a day from contaminated needles and other sharp devices. Data suggests that at least 65% of these injuries are preventable. The workbook, "Sharps Safety: Be Sharp. Be Safe," promotes a comprehensive prevention program in the healthcare setting that targets both healthcare administrators and frontline workers. For more information, visit

www.cdc.gov/sharpssafety/



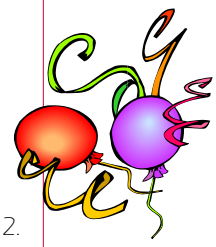
Ideas or suggestions for future communications, email leighann.bates@ky.gov

Environmental Samples

In no case should Sentinel Labs accept any environmental specimens to be examined or cultured for bioterrorism agents. If contacted, you should encourage the potential submitter to contact the State Public Health Lab for consultation.

502-564-4446

Non-working hours
888-9REPORT



Answers to Puzzler on page 2.

PUZZLER

Unscramble the letters to make a word. Using the letters in the circles, form a new word that everyone should be prepared for.

NSEILSL _OO____

MMPTOYS __O____

SHRA __O_

MUBPS ___O_

CBAS _O__

XAHO _O_O

__ __ __ __ __ __ __ __

CLIA UPDATES

Final Regulations published in Federal register 1/2004

- Category of testing—now either waived or non-waived
- Proficiency testing—each facility must grade all challenges even if not graded by PT agency. Non-graded specimens will have to be reviewed by each lab , and if you are not in the acceptable range, you will have to perform corrective action. It will no longer be acceptable to look at final score and accept satisfactory score without looking at each non-graded specimen.
- Inspection will be organized into the pre-analytical, analytical, and post analytical processes. Each phase of laboratory testing will have a quality assessment regulation. This involves a written policy and/or procedure for an ongoing mechanism to monitor, assess and correct problems identified in pre-analytical, analytical and post analytical phases of testing including a review of the effectiveness.

Pre-Analytical

- **Policy** to solicit written authorization within 30 days of an oral request - in SOPM. **Policy** what to do if written order is not received
- **Policy** for specimen collection, rejection
- **Policy** for specimen referral and transportation requirements
- Test request must include two patient identifiers—these must also appear on the specimen

Analytical

- **Policy** what steps are taken with change of Lab Director
- **Policy** for addition of new procedures
- **Policy** for deletion of old procedures
- **Policy** to establish criteria to modify manufacturer's procedures when applicable
- **Policy** on how to report results including panic values—when to call (time limit), who results are given to i.e. doctor or nurse

Post Analytical

- **Policy** on how to monitor positive identification of specimens
- **Policy** on how to identify who performed the test
- **Policy** on retention of all records
- **Policy** on who is responsible for receiving reference lab results. How to handle panic values from reference labs
- **Policy** on corrective actions—put steps in place to prevent error from reoccurring. Include identification, investigation, and resolution

Establishment and Verification of Test Procedures

- The laboratory must demonstrate they can obtain performance specifications comparable to those established by the manufacturer, in the laboratory's environment using the laboratory's personnel. This means that the manufacturer can no longer perform verification procedures for you. All testing personnel must be involved in the verification process.
- Verification must be performed prior to patient testing. You can establish your own number of samples to be used, but this needs to be in writing.
- Accuracy—you can pick how many samples you want to do. You must write this in the form of a **policy.**
- Precision—All testing personnel have to participate
- Reference Range—**Policy** on how many patients/ samples are used. You can use National Reference Range but you need to get Director's permission.

Calibration and Calibration Verification

- Calibration verification must be performed once every 6 months
- Calibration verification must be performed whenever a change of reagents for a procedure is introduced.
- Calibration verification must be performed when control material reflects a shift or trend. A **policy** needs to be in place that tells what actions will be performed (calibration, calibration verification, and some sort of investigation) if x number of values are on one side of the mean.

Survey Process 1st Cycle

- CLIA will site all condition—level deficiencies and those standard –level deficiencies having a direct link to patient outcome. However, no enforcement actions will be taken based on the final regulations until after they have worked closely with the lab to help them become compliant. If they find deficiencies based on the new regulations, educational approach will be used to help the lab stay in compliance. If they find deficiencies based on the old regulations, they will write and issue a Statement of Deficiencies.

Answers to Puzzler: Illness, Symptom, Rash, Bumps, Scab, Hoax
Final Word: SMALLPOX

100 Sower Blvd.
Suite 204
Frankfort, KY 40601

Phone: 502-564-4446
Fax: 502-564-7019
Email: xyz@microsoft.com

Your business tag line here.

We're on the Web!
example.microsoft.com

Organization

This would be a good place to insert a short paragraph about your organization. It might include the purpose of the organization, its mission, founding date, and a brief history. You could also include a brief list of the types of products, services, or programs your organization offers, the geographic area covered (for example, western U.S. or European markets), and a profile of the types of customers or members served.

It would also be useful to include a contact name for readers who want more information about the organization.

BACK PAGE STORY HEADLINE

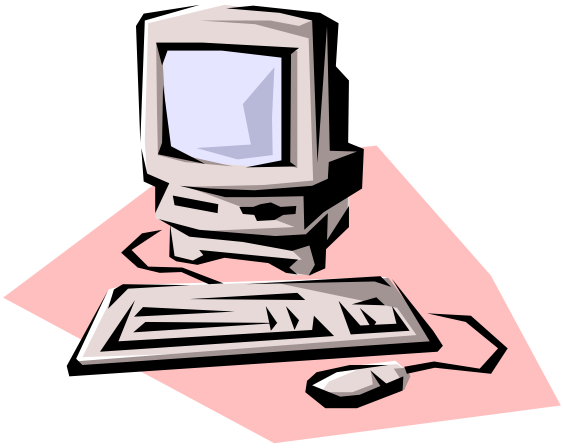
This story can fit 175-225 words.

If your newsletter is folded and mailed, this story will appear on the back. So, it's a good idea to make it easy to read at a glance.

A question and answer session is a good way to quickly capture the attention of readers. You can either compile questions that you've received since the last edition or you can summarize some generic questions that are frequently asked about your organization.

A listing of names and titles of managers in your organization is a good way to give your newsletter a personal touch. If your organization is small, you may want to list the names of all employees.

If you have any prices of standard products or services, you can include a listing of those here. You may want to refer your readers to any other forms of communication that you've created for your organization.



Caption describing picture or graphic.

You can also use this space to remind readers to mark their calendars for a regular event, such as a breakfast meeting for vendors every third Tuesday of the month, or a biannual charity auction.

If space is available, this is a good place to insert a clip art image or some other graphic.